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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001,

340B HEALTH,
1101 15th Street, NW, Suite 910
Washington, DC 20005, *et al.*,

Plaintiffs,

–v–

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 3:20-cv-08806

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR A PRELIMINARY INJUNCTION AND PERMANENT INJUNCTION

Filed Concurrently Herewith:

(1) Plaintiffs' Exhibits A–C; and

(2) Motion for Leave to Exceed Page Limit for Motion for Preliminary and Permanent Injunction

Date: TBD
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Action filed: December 11, 2020

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PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION

PLEASE TAKE NOTICE that on a date and time to be noticed later, in a court to be determined by judicial assignment, Plaintiffs, the American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists (collectively the "Association Plaintiffs") and Avera St. Mary's Hospital, Riverside Hospital, Inc., d/b/a Riverside Regional Medical Center, and Dignity Health d/b/a St. Mary's Medical Center (collectively the "Hospital Plaintiffs") will and hereby do move, pursuant to Rule 65 of the Federal Rules of Civil Procedure, for a preliminary and permanent injunction against Defendants Department of Health and Human Services ("HHS") and its Secretary, Alex M. Azar II.

As set forth below, Plaintiffs respectfully move this Court for a preliminary injunction directing Defendants to require Eli Lilly and Company, Sanofi-Aventis U.S. LLC, AstraZeneca PLC, Novartis Pharmaceuticals Corporation, United Therapeutics Corporation, and Novo Nordisk, Inc. and Novo Nordisk Pharma (collectively, the "Drug Companies") to provide drugs covered by the 340B Program, 42 U.S.C. § 256b, at the discounted prices required by law when the drugs are sold through outside pharmacies with which 340B covered entities have a contractual arrangement. Plaintiffs also move this Court to order Defendants to require the Drug Companies to refund the Hospital Plaintiffs and the Association Plaintiffs' members who are 340B covered entities the difference between what each covered entity paid for their covered outpatient drugs and the 340B ceiling price for the Drug Companies' drugs dispensed during the time the Drug Companies' illegal policies were in effect and to order Defendants to refer the matter to the HHS Office of the Inspector General for assessment of civil money penalties pursuant to 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003.

Alternatively, Plaintiffs respectfully move this Court to order Defendants to issue a decision, within 30 days, on whether the Drug Companies' decision not to sell 340B drugs at or below the 340B ceiling price when dispensed through contract pharmacies complies with the 340B statute and to inform the Court of their decision, and if Defendants determine that the Drug Companies' conduct violates the 340B statute to inform the Court as to the actions they will take to address that illegal conduct.

Plaintiffs also respectfully move for the Court to advance its determination of the merits pursuant to Rule 65(a)(2) and to issue a permanent injunction to the same effect.

This motion is based upon this Notice of Motion, the accompanying Memorandum of Points and Authorities; the accompanying declarations of Mikel Holland, MD, Cindy Williams, and Todd Strumwasser; all other pleadings or documents on file or to be filed, and any other written or oral evidence or argument presented at or before this motion is heard. Pursuant to Local Civil Rule 7.2, Plaintiffs respectfully request a hearing on their motion at the Court's earliest possible convenience.

MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION AND PERMANENT INJUNCTION

INTRODUCTION

This action challenges as a violation of the Administrative Procedure Act Defendants' failure to require Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), AstraZeneca PLC ("AstraZeneca"), Novartis Pharmaceuticals Corporation ("Novartis"), United Therapeutics Corporation ("United Therapeutics"), and Novo Nordisk, Inc. and Novo Nordisk Pharma ("Novo Nordisk") (collectively, the "Drug Companies") to comply with the statutory requirement to offer certain outpatient drugs to 340B hospitals at discounted prices when those drugs are dispensed through outside pharmacies via contractual arrangements.

Plaintiffs are three non-profit hospitals—Avera St. Mary's Hospital, Riverside Hospital, Inc. d/b/a Riverside Regional Medical Center ("Riverside") and Dignity Health d/b/a St. Mary's Medical Center ("SMMC") (collectively, the "Hospital Plaintiffs")—and six hospital/health system associations—the American Hospital Association ("AHA"), 340B Health, America's Essential Hospitals ("AEH"), the Association of American Medical Colleges ("AAMC"), the National Association of Children's Hospitals d/b/a/ the Children's Hospital Association ("CHA"), and American Society of Health-System Pharmacists ("ASHP") (collectively, the "Association Plaintiffs")—whose members include nonprofit hospitals and health systems that are impacted by the Drug Companies' contract pharmacy policies.

The Drug Companies' refusal to offer 340B drugs at discounted prices when dispensed through contract pharmacies is inconsistent with the 340B statute and with the Health Resources and Services Administration's ("HRSA") longstanding, correct interpretation of the 340B statute, jeopardizing hospitals' ability to care for patients during the most serious public health crisis in the last century.

More than 80% of rural 340B hospitals use contract pharmacies to ensure their patients have access to needed outpatient drugs, as well as other essential services.[1] If permitted to stand, the Drug Companies' decision not to comply with the 340B statute will continue to have devastating consequences for 340B hospitals and the patients they serve.

STATEMENT OF FACTS

A. The 340B Program

Congress created the 340B Program in 1992 to provide certain hospitals, community health centers, and other federally funded clinics serving low-income patients ("340B providers")[2] with outpatient drug discounts comparable to those Congress had made available to state Medicaid agencies in 1990. *See* Veterans Health Care Act of 1992, Pub. L. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992) (codified as amended at 42 U.S.C. § 256b). After Congress had passed the Medicaid drug rebate program, it became concerned that federally funded clinics and public hospitals were experiencing substantial increases in their outpatient drug costs. H.R. REP. No. 102–384(II), at 11 (1992). Therefore, under the 340B Program, as a condition of having their outpatient drugs covered through Medicaid and Medicare Part B (the Medicare program that provides hospital outpatient and physician services), prescription drug companies are required to enter into a 340B Pharmaceutical Pricing Agreement ("PPA") with the Secretary of Health and Human Services ("HHS" or the "Secretary"), pursuant to which they must offer 340B providers outpatient drugs at or below a discounted, statutorily determined price referred to as the "ceiling price." 42 U.S.C. § 256b (a)(1).

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[1] Fact Sheet: 340B Drug Pricing Program − Contract Pharmacy Arrangements, Am. Hosp. Ass'n (Oct. 2020), https://www.aha.org/system/files/media/file/2020/10/fact-sheet-340b-drug-pricing-program-contract-pharmacy-arrangements.pdf.

[2] The statute refers to 340B providers as "covered entit[ies]." 42 U.S.C. § 256b(a)(4).

The ceiling price—the maximum per-unit price that can be charged to 340B providers for outpatient drugs—determines the discounts made available under the 340B Program. The mandated discount is a minimum of 23.1% for brand name drugs or 13% for generic drugs. 42 U.S.C. § 1396r-8(c)(1). According to HRSA, which is responsible for administering the 340B Program, 340B providers can achieve average savings of 25% to 50% in pharmaceutical purchases.[3] According to a 2019 survey, the median 340B benefit ranged from $564,000 for Critical Access Hospitals to $12.6 million for Children's Hospitals. Disproportionate Share Hospitals ("DSH") had a median benefit of $8.9 million.[4]

Congress enacted the 340B Program "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. NO. 102-384(II), at 12 (1992). A 2011 report from the U.S. Government Accountability Office ("GAO") found that the 340B Program has had this exact effect and that 340B providers have used the funds made available through the drug discounts to provide critical health care services to communities with underserved populations that could not otherwise afford these services—for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services. U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17-18 (Sept. 2011) ("2011 GAO Report"), http://www.gao.gov/assets/330/323702.pdf.

3 *Justification of Estimates for Appropriations Committees (Fiscal Year 2021)*, HRSA, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf; *Justification of Estimates for Appropriations Committees (Fiscal Year 2020)*, HRSA, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2020.pdf.

4 *2019 340B Health Annual Survey: 340B Hospitals Use Benefits to Provide Services and Improve Outcomes for Low-Income and Rural Patients*, 340B Health (April 2020), https://www.340bhealth.org/files/340B-Health-Survey-Report-2019-FINAL.pdf.

Recognizing the value of the 340B Program, Congress expanded and made other improvements to the Program as part of the 2010 Affordable Care Act ("ACA"). *See* Patient Protection and Affordable Care Act, Pub. L. 111-148, §§ 7101–7103, 124 Stat. 119, 821–28 (2010) (codified at 42 U.S.C. § 256b). Among other things, Congress recognized that to "improve . . . compliance by manufacturers," there needed to be a threat of financial penalties to "prevent overcharges and other violations of the discounted pricing requirements." 42 U.S.C. § 256b(d)(1)(A). Therefore, Congress required the Secretary to impose "sanctions in the form of civil monetary penalties" against drug companies that "knowingly and intentionally" "overcharg[e] a covered entity," up to $5,000 "for each instance of overcharging." *Id.* § 256b(d)(1)(B)(vi).

The regulations governing 340B civil monetary penalties state that "[a]n instance of overcharging is any order for a covered outpatient drug . . . which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." 42 C.F.R. § 10.11(b). Importantly, "[t]his includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.* § 10.11(b)(1).

In addition, Congress directed the Secretary to "establish[] procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including . . . [o]versight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustments to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs." 42 U.S.C. § 256b(d)(1)(B)(ii). HRSA has adopted a process pursuant to which covered entities

can submit information concerning overcharges directly to HRSA on a form that has been developed by HRSA's 340B prime vendor.[5]

B. Contract Pharmacies

340B providers dispense covered outpatient drugs to their patients through in-house pharmacies and through outside pharmacies that have entered into written contracts with the providers ("contract pharmacies"). Under such arrangements, the 340B provider orders and pays for the 340B drugs, which are then shipped to the contract pharmacy where the drugs are dispensed to the 340B provider's patients.

Since the beginning of the 340B program, HRSA has stated that the 340B statute requires drug manufacturers to provide 340B providers their drugs at 340B ceiling prices even if they are being dispensed by a contract pharmacy. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). In 1996 HRSA noted that "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified groups of 340B covered entities." *Id.* at 43,549. Importantly, HRSA declared that under section 340B, "*if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price*." *Id.* at 43,555 (emphasis added).

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[5] HRSA's prime vendor has created a form, which is available at: https://docs.340bpvp.com/documents/public/resourcecenter/HRSA_Notification_340B_Price_Unavailable.docx. The 340B Prime Vendor Program provides free technical assistance to all 340B stakeholders to support their management of 340B-compliant operations. The 340B Prime Vendor Program, as part of its agreement with HRSA, provides online tutorials, a variety of templates, and other tools to aid with program compliance. In addition, under the terms of the agreement with HRSA, it offers two educational programs and a national call center. 340B Educational Resources, HRSA, https://www.hrsa.gov/opa/educational-resources/index.html.

Although HRSA's initial focus was on entities that did not have access to "in-house" pharmacy services, HRSA has recognized that it would be appropriate for any 340B provider to use a contract pharmacy. *Id.* at 43,551. Moreover, although HRSA initially had concerns about drug diversion that led to its early guidance limiting entities to a single contract pharmacy, it subsequently determined that this was not an issue and revised its guidance to explicitly recognize that covered entities could use more than one contract pharmacy. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). In finalizing that guidance, HRSA again recognized that "[u]nder section 340B, *if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price*." *Id.* at 10,278 (emphasis added).

For more than 20 years, all drug companies, including Lilly, Sanofi, AstraZeneca, Novartis, United Therapeutics, and Novo Nordisk accepted 340B providers' right to have their 340B discounted drugs shipped to contract pharmacies. Overall, a quarter of the average 340B benefit comes from contract pharmacy arrangements. This varies by hospital type, with Critical Access Hospitals reporting receiving an average of 57%of their 340B benefit from contract pharmacy arrangements, while DSH hospitals report receiving an average of 24% of their 340B benefit from contract pharmacy arrangements.[6]

C. The Drug Companies' Refusal to Give 340B Discounts

Over the course of the last five months, the Drug Companies have abandoned their 20-year compliance with the statutory requirement to provide 340B providers with drugs at or below 340B

[6] *2019 340B Health Annual Survey*, https://www.340bhealth.org/files/340B-Health-Survey-Report-2019-FINAL.pdf.

ceiling prices and have refused to offer 340B discounts for covered drugs if a 340B provider orders the drugs to be dispensed through nearly all contract pharmacies.

In June 2020, HRSA posted a notice from Eli Lilly stating that, effective July 1, 2020, the company would no longer provide 340B pricing on three formulations of its drug Cialis® when the 340B provider purchasing the drug elects to have it shipped to a contract pharmacy.[7] The notice indicated that Lilly would make an exception for entities that do not have their own in-house pharmacy.[8] On or around September 1, 2020, Lilly issued another notice extending its refusal to provide 340B discounts to 340B providers to all Lilly drugs when dispensed through contract pharmacies, effective September 1, 2020, with the same exception for providers without an in-house pharmacy and a complicated exception process for insulin products.[9]

In July 2020, Sanofi joined Lilly and notified covered entities that, effective October 1, 2020, it was requiring 340B covered entities to submit claims data for 340B prescriptions of Sanofi products filled through contract pharmacies and that covered entities that do not provide such claims data are no longer eligible to order Sanofi drugs at 340B prices if those drugs are dispensed through contract pharmacies.[10]

On August 17, 2020, AstraZeneca jumped on board and issued notices to 340B providers stating that, effective October 1, 2020, the company "only will process 340B pricing through a single Contract

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7 *See* Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

8 *See id.*

9 *See* Limited Distribution Plan Notice for Eli Lilly and Company Products, https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.

10 Sanofi Notice (July 2020), https://www.340bhealth.org/files/Sanofi_Notice_10_1_20.pdf.

Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy."[11]

Also on August 17, 2020, Novartis became the fourth pharmaceutical manufacturer to change its policy with respect to contract pharmacies, but with a new approach. Novartis first notified covered entities that, effective October 1, 2020, "all 340B covered entities will be required to . . . provide 340B claims data originating from [contract pharmacy] utilization in order to receive 340B reimbursements from Novartis."[12] Then, on October 30, 2020, Novartis announced that it will honor contract pharmacy arrangements within a 40-mile radius of a 340B hospital's main campus, but not for hospitals that have arrangements with pharmacies outside a 40-mile radius.[13]

On November 18, 2020, United Therapeutics became the fifth drug manufacturer to announce restrictions related to contract pharmacies, informing covered entities that the company would institute its changes in two phases. First, beginning November 20, 2020, United Therapeutics is accepting 340B contract pharmacy orders only if the contract pharmacy was utilized by the covered entity for a *valid 340B purchase* of a United Therapeutics covered outpatient drug during the first three full quarters of the 2020 calendar year.[14] The announcement provided a link that is supposed to identify which contract

[11] Letter Re: 340B Contract Pharmacy Pricing, AstraZeneca (Aug. 17, 2020), https://www.dropbox.com/s/gethwns6m7zzkoh/AstraZeneca%20Retail%20Communication%20-%20340B%20-%20Final.pdf?dl=0.

[12] *E.g.*, Letter, Novartis (Aug. 17, 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Novartis-letter-requesting-data-08.17.2020.pdf.

[13] New policy related to the 340B program, Novartis (Oct. 30, 2020), https://www.novartis.us/news/statements/new-policy-related-340b-program.

[14] Letter Re: United Therapeutics Corporation 340B Contract Pharmacy Policy Effective November 20, 2020, United Therapeutics Corp. (Nov. 18, 2020), https://www.dropbox.com/s/swyrookjcwqxe58/United%20Therapeutics%20Letter%2011.20.2020%20%281%29.pdf?dl=0. United Therapeutics excepted ADCIRCA, a form of tadalafil indicated for pulmonary hypertension that Lilly manufactures for United Therapeutics, from both phases of its new policy but otherwise included no exception as to the second phase, even for covered entities with no in-house pharmacy.

pharmacies are eligible for this phase, though to date that link does not include that information. Covered entities without on-site pharmacies can apply for an exception that would allow the covered entity "to designate a single contract pharmacy for which United Therapeutics Corporation will accept 340B orders." United Therapeutics further announced that, in the second phase, the company "will accept 340B contract pharmacy orders placed on or after May 13, 2021 only if the covered entity also has agreed to provide to United Therapeutics Corporation, and is providing on an ongoing basis, claims data associated with all 340B contract pharmacy orders of United Therapeutics Corporation's covered outpatient drugs placed after May 13, 2021."

On December 1, 2020, Novo Nordisk announced that on January 1, 2021, it would join the other five drug manufacturers in imposing restrictions related to 340B contract pharmacies. Novo Nordisk's policy will apply only to hospitals and includes an exception for hospitals that do not have their own on-site pharmacy.[15]

D. HRSA's Response to the Drug Companies' New Policies

On July 8, 2020, after Lilly announced its decision to stop offering Cialis® at 340B ceiling prices to 340B providers using contract pharmacies, plaintiff 340B Health asked HRSA whether it "considers Lilly's decision to be compliant with [the] 340B statute and/or guidance." On that same day, HRSA responded that contract pharmacies "serve a vital function in covered entities' ability to serve underserved and vulnerable populations" and that "[m]anufacturers that refuse to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for

[15] Notice Regarding Limitation on Hospital Contract Pharmacy Distribution, Novo Nordisk (Dec. 1, 2020), https://www.340bhealth.org/files/Novo_Nordisk_12-1-2020.pdf.

many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions."[16]

As to 340B Health's specific question of whether Lilly's policy was compliant with the statute and HRSA guidance, HRSA acknowledged that its 2010 guidance recognized contract pharmacies but stated that "HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute." It then stated that "[w]ithout comprehensive regulatory authority, HRSA is unable to develop an enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B program." Thus, while acknowledging that it has enforcement authority against violations of the 340B statute, HRSA claimed that in this circumstance its hands are tied and it cannot act to bring the Drug Companies into compliance with the law. The basic issue in this lawsuit is whether HRSA was correct when it decided that it lacked legal authority to require the Drug Companies to provide 340B drugs at or below 340B ceiling prices when dispensed through contract pharmacies.

The Association Plaintiffs, as well as numerous other associations and 340B providers concerned with the Drug Companies' illegal policies, contacted Defendants and requested that they fulfill their statutory duty of enforcing the requirement that the Drug Companies provide 340B drugs sold through contract pharmacies at or below 340B ceiling prices to 340B providers. On July 16, 2020, 340B Health, along with other organizations representing 340B providers, sent a letter to the Secretary asking him to "use [HHS's] legal authority to halt these actions and protect vital institutions and their

[16] Email from Martin Kramer to Richard Sorian (July 8, 2020), https://www.340bhealth.org/files/HRSA_Response_on_Eli_Lilly_-_07-08-2020.pdf.

patients."[17] On July 30, 2020, the AHA sent a letter to the Secretary asking him to "address these abuses . . . and request [the Drug Companies] cease this activity and work to ensure 340B drugs are available and accessible to communities and vulnerable populations."[18]

On August 28, 2020, AEH sent a letter to the Secretary asking "the agency to intervene to prevent manufacturers from undermining the 340B program and violating their statutory obligations."[19] And on September 10, 2020, Avera St. Mary's Hospital and SMMC joined a letter to the Secretary signed by more than 1,100 340B hospitals stating that the Drug Companies' "collective actions to deny access to 340B pricing are clear violations of the 340B statute" and urging the Secretary to use his authority to end these practices.

AHA sent additional letters to the Secretary on September 8, 2020 ("[W]e urge you to act immediately against any drug manufacturer employing these pernicious tactics to ensure that 340B drugs are available and accessible to vulnerable communities."),[20] and October 16, 2020 ("[W]e request that HHS immediately direct [Lilly, AstraZeneca, and Sanofi] to cease charging hospitals and covered entities more than the 340B ceiling price for drugs being dispensed by a contract pharmacy and . . . to issue refunds for each overcharge instance. We also request that the matter be referred to the HHS Office of Inspector General for assessment of civil money penalties.").[21]

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[17] Letter Re: Recent Actions by Pharmaceutical Manufacturers Eli Lilly and Merck Impacting 340B Covered Entities, 340B Coalition (July 16, 2020), http://nysarh.org/wp-content/uploads/2020/08/340B-Coalition-Letter-Final-7.16.20.pdf.

[18] Letter, AHA (July 30, 2020), https://www.aha.org/system/files/media/file/2020/07/aha-urges-hhs-take-action-against-drug-manufacturers-for-limiting-distribution-340b-drugs-letter-7-30-2020.pdf.

[19] Letter Re: Pharmaceutical Company Actions Undermining 340B Drug Pricing Program, AEH (Aug. 28, 2020), https://essentialhospitals.org/wp-content/uploads/2020/08/AEH-Letter-340B-Contract-Pharmacy-8-28-20.pdf.

[20] Letter, AHA (Sept. 8, 2020), https://www.aha.org/system/files/media/file/2020/09/aha-again-urges-hhs-to-protect-340b-program-from-drug-companies-actions-letter-9-8-20.pdf.

[21] Letter, AHA (Oct. 16, 2020), https://www.aha.org/system/files/media/file/2020/10/aha-urges-hhs-stop-drug-companies-refusal-provide-required-340b-discounts-letter-10-16-20.pdf.

On September 21, 2020, in response to a letter from Lilly, HHS's General Counsel Robert Charrow expressed "significant" concerns with Lilly's new policy and stated the agency was considering whether to take action against Lilly.[22] To date, the General Counsel has not announced any action against Lilly or the other Drug Companies. On December 9, 2020, HRSA sent a similar letter to 340B Health.[23]

ARGUMENT

A preliminary injunction is appropriate in this case because (1) Plaintiffs are likely to succeed on the merits; (2) Plaintiffs are likely to suffer irreparable harm in the absence of injunctive relief; (3) the balance of equities favor Plaintiffs; and (4) an injunction is in the public interest. *See A Woman's Friend Pregnancy Resource Clinic v. Becerra*, 901 F.3d 1166, 1167 (9th Cir. 2018) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)); *see also Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011) (explaining that "serious questions going to the merits and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest") (internal quotation marks omitted). "When the government is a party," courts in the Ninth Circuit "consider the balance of equities and the public interest together." *Envt'l Protection Info. Ctr. v. Carlson*, 968 F.3d 985, 991 (9th Cir. 2020) (internal quotation marks and citation omitted).

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[22] Letter from Robert Charrow to Anat Hakim, Lilly (Sept. 21, 2020) https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

[23] Letter from Krista M. Pedley to Maureen Testoni (Dec. 9, 2020), https://www.340bhealth.org/files/HRSA_Response_Letter_-_12-09-2020.pdf.

I. EACH OF THE PRELIMINARY INJUNCTION FACTORS FAVORS GRANTING PLAINTIFFS' MOTION.

A. Plaintiffs Are Likely to Succeed on the Merits.

The fundamental legal issue in this case is whether the 340B statute requires drug manufacturers to offer covered outpatient drugs to 340B providers at or below 340B ceiling prices when those providers have the drugs delivered to a contract pharmacy. As demonstrated below, the answer is unambiguously "yes," because the statute directs drug manufacturers that participate in the program to offer 340B drugs at the mandated 340B prices, and nothing in the statute authorizes manufacturers to limit discounts on the basis of how 340B providers deliver 340B drugs to their patients. Whether HRSA's regulatory guidelines are legally binding is beside the point, as HRSA has the obligation to enforce the legally binding statute. HRSA's regulatory action thus violates both the 340B statute and the Administrative Procedure Act.

1. HRSA Has the Legal Authority to Require the Drug Companies to Comply with the 340B Statute and to Offer 340B Drugs at the 340B Ceiling Prices When Distributed to Patients Through Contract Pharmacies.

Under the 340B statute, drug companies, as a condition of having their outpatient drugs covered through Medicaid and Medicare Part B, are required to enter into a PPA with the Secretary, pursuant to which they must agree to offer 340B providers covered outpatient drugs at or below the 340B ceiling price. The 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer . . . does not exceed an amount equal to the average manufacturer price for the drug . . . reduced by the rebate percentage." 42 U.S.C. § 256b(a)(1). The statute goes on to define "the rebate percentage" as equal to "the average total rebate required under section 1927(c) of the Social

Security Act [42 U.S.C. § a1396r–8(c)]," which is currently a minimum of 23.1% for brand drugs and 13% for generic drugs. *Id.* § 256b(a)(2).

The statute places no limitation on how 340B providers must make those drugs available to their patients nor does it authorize manufacturers to impose such limitations. Thus, under the terms of the 340B statute and the PPAs that Lilly, AstraZeneca, Sanofi, Novartis, United Therapeutics, and Novo Nordisk entered into with HRSA, all six companies are required to charge all 340B providers no more than the 340B ceiling price for any covered outpatient drug, whether it is delivered to the provider's in-house pharmacy or to a pharmacy that has entered into a contract with the provider to furnish 340B drugs to the provider's patients. Failure to do so violates the 340B statute and the PPAs and subjects the Drug Companies to enforcement actions. It is HRSA's responsibility to enforce that statutory obligation.

The Drug Companies claim that the restrictions they have adopted are designed to prevent drug diversion (selling the drug to persons who are not patients of the covered entity) and duplicate discounts (drug manufacturers are not required to offer a drug at the 340B discount rate to covered entities and pay rebates to state Medicaid programs for the same drug).[24] Even if there were a legitimate basis for this concern, which there is not, nothing in the statute gives drug manufacturers the authority to unilaterally stop providing 340B discounts as a way to address the potential for drug diversion or duplicate discounts. Instead section 340B gives drug manufacturers specific tools to protect against this

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[24] *See, e.g.*, Notice, Sanofi (Oct. 1, 2020), https://www.dropbox.com/s/mjjm1a44l5ekmoe/Text%20of%20Sanofi%20email%20to%20340B%20covered%20entity%2010.1.2020.pdf?dl=0; Letter, Novartis (Aug. 17, 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Novartis-letter-requesting-data-08.17.2020.pdf; Letter Re: Availability of 340B-Priced Cialis® (tadalafil) Erectile Dysfunction Presentations to Contract Pharmacies, Lilly (May 18, 2020), https://www.dropbox.com/s/ttjou3z9zo7q33w/Lilly%20letter%20to%20HRSA%2005.18.2020.pdf?dl=0.

type of unlawful conduct, namely the authority to audit the records of 340B providers. 42 U.S.C. § 256b(a)(5)(C). If after such an audit and a hearing, the Secretary (not the manufacturer) finds that the covered entity has violated the prohibition on diversion or duplicate discounts, the covered entity must pay a refund to the manufacturer. *Id.* § 256b(a)(5)(D). Manufacturers may not, of their own volition, stop providing 340B discounts.

The basis for HRSA's decision that it cannot require manufacturers to sell their drugs at or below the 340B ceiling price when shipped to contract pharmacies was its observation that its 2010 contract pharmacy guidance (75 Fed. Reg. 10,272) is not legally binding. But HRSA's decision misses the basic point that *statutes* are binding and that it is HRSA's core obligation to inform the Drug Companies that they are violating the statute and to enforce the statute if they refuse to comply.

In other words, contrary to HRSA's statement, the fact that its contract pharmacy guidance is not legally binding is not a barrier to requiring that the Drug Companies give 340B discounts when drugs are sold at contract pharmacies. As HRSA has acknowledged many times over many years, the statute requires the Drug Companies to offer 340B providers covered outpatient drugs at or below the 340B ceiling price regardless of whether the drug is delivered to a contract pharmacy. The guidance accurately describes a statutory requirement and has provided the Drug Companies with notice of HRSA's correct interpretation of the statute.

Indeed, HRSA's prior interpretations of the 340B statute confirm the merits of Plaintiffs' claims. HRSA's determination that it cannot require the Drug Companies to give 340B discounts for drugs distributed through contract pharmacies is incompatible with statements the agency has made since the beginning of the 340B Program. HRSA has repeatedly recognized the statutory requirement to provide 340B entities covered drugs at or below 340B ceiling prices when they are dispensed by a

contract pharmacy. These statements have been consistent and comprehensive, and they show how, since the inception of the 340B Program, HRSA has never wavered in its interpretation of the statute.

In 1996, HRSA issued "final guidelines" which recalled that since the beginning of the 340B Program, HHS has recognized that 340B providers are permitted to use contract pharmacies to dispense 340B drugs, so long as they comply with the prohibition on drug diversion. 61 Fed. Reg. at 43,550 ("As early as 1993, several covered entity groups . . . came forward to assist the Department in developing a workable mechanism to use outside pharmacies."). At the same time, HRSA noted that "[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself" and that "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.* at 43,549.

In fact, HRSA recognized that "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients" and that "even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs." *Id.* at 43,550. HRSA agreed with commenters that "[b]y issuing guidelines . . . , [the Office of Drug Policy, a Division of HRSA, was] not seeking to create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under State law." *Id.* at 43,550. Finally, HRSA stated that "[u]nder section 340B, . . . *if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price*." *Id.* at 43,555 (emphasis added).

In sum, under the terms of the 340B statute, HRSA had the authority to direct and should have directed Lilly, AstraZeneca, Sanofi, Novartis, United Therapeutics, and Novo Nordisk to charge no more than the 340B ceiling price for covered outpatient drugs in every case, including where those

drugs are delivered to a contract pharmacy, and to refund 340B providers for the difference between what the provider has paid for their covered outpatient drugs and the 340B ceiling price. In addition, because the statute requires the Secretary to impose "sanctions in the form of civil monetary penalties" against drug companies that "knowingly and intentionally" "overcharg[e] a covered entity," up to $5,000 "for each instance of overcharging," 42 U.S.C. § 256b(d)(1)(B)(iv), HRSA also should have referred the matter to the HHS Office of the Inspector General for assessment of civil money penalties pursuant to 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003.

2. Defendants' Failure to Enforce the 340B Statute Violates the Administrative Procedure Act.

Defendants' decision that HRSA lacks authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices to covered entities that dispense those drugs through contract pharmacies is contrary to law, in violation of section 706(2)(A) of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A), and Defendants' failure to take actions to assure that the law is followed is arbitrary and capricious and an abuse of discretion, also in violation of section 706(2)(A).

The APA provides a cause of action for individuals aggrieved by a final agency action if there is no other remedy in a court. *Id.* § 704. Pursuant to section 706(2)(A) of the APA, "a reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A).

HRSA's decision that it may not use its enforcement authority to require the Drug Companies to provide covered outpatient drugs at or below 340B ceiling prices to a covered entity for dispensing to the entity's patients from a contract pharmacy is not in accordance with the law because, as described above, it is flatly inconsistent with the plain language of the statute. It also conflicts with HRSA's longstanding interpretation of the statute.

For an action to be "final" it must (1) "mark the consummation of the agency's decision-making process"—it must not be of a merely tentative or interlocutory nature; and (2) "be one by which rights or obligations have been determined, or from which legal consequences will flow." *Gill v. Dep't of Justice*, 913 F.3d 1179, 1184 (9th Cir. 2019) (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). The Ninth Circuit focuses on "the practical and legal effects of the agency action" and interprets finality in a "pragmatic and flexible manner." *Id.* (quoting *Or. Nat. Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006)).

Defendants' decision constitutes final agency action, as it marked the consummation of the decision-making process with respect to what authority Defendants have concluded HRSA possesses, and it prevented the agency from bringing actions against the Drug Companies, resulting in Plaintiffs' inability to purchase the Drug Companies' products at or below 340B ceiling prices despite having sought redress from HRSA. HRSA's action had a "direct and immediate effect on the day-to-day operations" of Plaintiffs. *Indus. Customers of Nw. Util. v. Bonneville Power Admin.*, 408 F.3d 638, 646 (9th Cir. 2005). Thus, HRSA's incorrect interpretation of the statute "affected the legal rights of the relevant actors." *Bennett*, 520 U.S. at 178. Although General Counsel Charrow's letter signaled the agency's intent to reconsider HRSA's July final decision, it does not change the fact that HRSA's earlier action was final. *See Ctr. for Biologic Diversity v. U.S. Bureau of Land Mgmt.*, No. CV 17-8587-GW, 2018 WL 3004594, at *10 (C.D. Cal. 2018) (that agency's decision could be modified irrelevant to finality). Nor did it change the fact that the Drug Companies have relied on and acted upon HRSA's decision that it has no authority even to inform them that their conduct is illegal, to the detriment of the Hospital Plaintiffs and the Association Plaintiffs' members.

In addition, Plaintiffs are completely dependent on HRSA to take action because the United States Supreme Court has held that 340B covered entities have no private right of action against the

Drug Companies, even though they have violated the 340B statute. *See Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 113–14 (2011). Only HRSA can require the Drug Companies to give the 340B covered entities the relief to which they are entitled. Defendants' decision that it cannot take actions to assure that the law is followed is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of section 706(2)(A).

3. If HRSA's Response Is Not Final Agency Action, HRSA's Failure to Issue a Final Decision Violates the APA's Prohibition on Agency Action Unlawfully Withheld or Unreasonably Delayed.

If this Court were to find that there has not been final agency action by HRSA, Plaintiffs are still likely to succeed on the merits because HRSA's failure to issue a final decision regarding the legality of the Drug Companies' policies violates the APA's prohibition on "unlawfully withheld or unreasonably delayed" agency action. *See* 5 U.S.C. § 706(1) (requiring courts to "compel agency action unlawfully withheld or unreasonably delayed").

"[T]he operation of § 706(1) is restricted to discrete actions that are unequivocally compelled by statute or regulation." *Vietnam Veterans of Am. v. Cent. Intelligence Agency*, 811 F.3d 1068, 1075 (9th Cir. 2016) (citing *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63–64 (2004)). Here, the 340B statute unequivocally compels HRSA to take action. Section 340B directs HRSA to oversee drug manufacturers to "ensure that refunds are issued accurately and within a reasonable period of time . . . [in] exceptional circumstances such as . . . intentional overcharging for covered outpatient drugs." 42 U.S.C. § 256b(d)(1)(B)(ii)(II). HRSA is failing to ensure that 340B covered entities are issued refunds for the Drug Companies' intentional overcharging.

To determine whether agency delays are unreasonable, courts in the Ninth Circuit use a six-factor test: (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) whether there is a congressional timetable or other indication of speed with which Congress expects

the agency to proceed and which may supply the basis for the "rule of reason"; (3) whether the delay is to an economic regulation, which is more tolerable than delays when human health and welfare are at stake; (4) the effect of expediting delayed action on agency priorities of a higher or competing priority; (5) the nature and extent of the interests prejudiced by the delay; and (6) whether there was "impropriety" in the agency's delay, although the court is not required to find any. *Telecomm. Research & Action Ctr. (TRAC) v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) (cited by *Indep. Mining Co. v. Babbitt*, 105 F.3d 502, 507 (9th Cir. 1997)).

Although there is no congressional timetable for HRSA to take action, a "rule of reason" test weighs in favor of Plaintiffs' claims. Plaintiffs and other 340B providers that rely on contract pharmacies are being deprived of the applicable discounts on covered drugs each and every time one of their patients fills a prescription for a Lilly, AstraZeneca, Sanofi, (sometimes) United Therapeutics, Novo Nordisk, or (sometimes) Novartis drug at one of their contract pharmacies. Because so many of these entities are financially strapped and some are already operating in the red, they cannot afford to wait to be reimbursed for the overcharges. *See* Decl. of Mikel Holland, MD ("Holland Decl."), Ex. A, ¶ 15; Decl. of Cindy Williams ("Williams Decl."), Ex. B, ¶ 12; Decl. of Todd Strumwasser ("Strumwasser Decl."), Ex. C, ¶ 13. Moreover, Defendants' delay has caused an increasing number of drug companies to join Lilly in refusing to provide 340B discounts for contract pharmacies. The Hospital Plaintiffs and the Association Plaintiffs' members will be increasingly harmed until Defendants act to declare and enforce the law.

Factors three and five also weigh in Plaintiffs' favor because human health and welfare are being impacted. As the losses grow, the impact those losses' have on Plaintiffs' underserved patients grows. And all of this is happening in the midst of a pandemic, which is disproportionately affecting

the communities 340B providers serve.[25] 340B providers are trying to respond to the immense financial and operational challenges posed by the COVID-19 public health emergency and trying to care for communities ravaged by the public health crisis while the Drug Companies' policies are exacerbating financial pressures. *See, e.g.*, Holland Decl., ¶ 13 (Avera St. Mary's Hospital stands to lose approximately $3.5 million if all drug manufacturers impose contract pharmacy restrictions and at least $1 million even if the restrictions are limited to the six companies at issue); Williams Decl., ¶ 11 (Riverside stands to lose $16 million if all drug companies impose contract pharmacy restrictions). The longer HRSA delays action, the greater the effect on human health and welfare. *See* Strumwasser Decl., ¶ 12 (If the current restrictions to 340B drug pricing for contract pharmacies are permitted to continue, or expand to other companies, SMMC's ability to serve the most vulnerable patients will be curtailed or, in some cases, eliminated); Holland Decl., ¶ 16 (Avera St. Mary's Hospital will be forced to evaluate and likely curtail some of the important programs through which it provides uncompensated care to the communities it serves); Williams Decl., ¶ 13 (If the current restrictions are permitted to continue, Riverside will be forced to provide fewer services and serve fewer patients. This could include eliminating its Level 2 Trauma Program, its 24/7 Sexual Assault Nurse Examiner Program, and/or its Dedicated Behavior Health Facility).

Finally, factor four also weighs in Plaintiffs' favor because the action Plaintiffs are requesting requires minimal use of agency resources, making the failure to act that much more unreasonable. *Cf.*

[25] *See, e.g.*, Caitlin Brown & Martin Ravallion, *Poverty, inequality, and COVID-19 in the US*, VOXEU (Aug. 10, 2020), https://voxeu.org/article/poverty-inequality-and-covid-19-us; Samrachana Adhikari et al., *Assessment of Community-Level Disparities in Coronavirus Disease 2019 (COVID-19) Infections and Deaths in Large US Metropolitan Areas*, JAMA (July 28, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768723?resultClick=1; Wyatt Koma et al., *Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus*, Kaiser Family Found. (May 7, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/low-income-and-communities-of-color-at-higher-risk-of-serious-illness-if-infected-with-coronavirus/.

Doe v. Risch, 398 F. Supp.3d 647, 658 (N.D. Cal. 2019) (finding that "the fourth factor tips in Plaintiffs' favor" because expediting delayed agency action "would not unduly burden agency resources").

B. Plaintiffs Will Suffer Irreparable Harm in the Absence of the Requested Preliminary Injunction.

A showing of irreparable harm has two components. First, the claimed harm must be "not remote or speculative, but actual and imminent." *Conroy's, Inc. v. Hejazi*, No. C 06-1684, 2006 WL 8442694, at *3 (N.D. Cal. July 18, 2006); *see also Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1022 (9th Cir. 2016) (noting that "a plaintiff must demonstrate immediate threatened injury as a prerequisite to preliminary injunctive relief") (emphasis and citation omitted). Second, the harm must be one "for which monetary damages cannot adequately compensate." *Conroy's*, 2006 WL 8442694, at *3; *see also Ariz. Dream Act Coalition v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014) ("Irreparable harm is traditionally defined as harm for which there is no adequate legal remedy, such as an award of damages."). "The analysis focuses on irreparability, irrespective of the magnitude of the injury." *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (internal quotation marks and citation omitted). Plaintiffs in this case satisfy both of these requirements.

The harms Plaintiffs allege in this case are actual and imminent. As set forth in the declarations attached hereto as Exhibits A, B, and C, the policies that are the subject of this lawsuit are resulting in dramatic and automatic lost revenue for each of the Hospital Plaintiffs (each of which is a member of one or more of the Association Plaintiffs). *See, e.g.*, Holland Decl., ¶ 13 (Avera St. Mary's Hospital stands to lose approximately $3.5 million if all drug manufacturers impose contract pharmacy restrictions and at least $1 million even if the restrictions are limited to the six companies at issue); Williams Decl., ¶ 11 (Riverside stands to lose $16 million if all drug companies impose contract

pharmacy restrictions). Thus, the effect of these policies on Plaintiffs is certain, immediate, and dramatic.

Nor is there any doubt that the harms caused by the policies at issue are beyond remediation. As noted above, the loss of funds caused by the Drug Companies' elimination of 340B discounts has an immediate impact on Plaintiffs' ability to adequately serve patients during the pandemic. Even if the lost funds could be recouped, any temporary suspension of services or denial of those services to hospitals' patients during that temporary period causes harm that can not be remedied by offering those services at a later time. *See Harris v. Bd. of Supervisors, L.A. Cty.*, 366 F.3d 754, 766 (9th Cir. 2004) (finding irreparable harm likely due to "delayed treatment" at health care centers and noting that "faced with a conflict between financial concerns and preventable human suffering, the court has little difficulty concluding that the balance of hardships tips decidedly in plaintiffs' favor") (internal quotation marks, citation, and alterations omitted); *Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 243 (D.D.C. 2014) (granting preliminary injunction and finding irreparable harm where plaintiff hospitals would be subject to recoupment of Medicaid payments by Centers for Medicare & Medicaid Services and noting that "[p]laintiffs . . . are not for-profit entities facing the loss of profit; rather, they are non-profits for whom lost funds would mean reducing hospital services for children"). Put simply, a hospital denied funds to provide services on Day 1 is not made whole by the restoration of funds enabling it to provide the same services on Day 2. *Cf. Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983) (noting in context of challenge to denial of social security benefits that, where "economic hardship, suffering or even death" are likely for individuals, "[r]etroactive restoration of benefits would be inadequate to remedy these hardships"); *Tex. Children's Hosp.*, 76 F. Supp. 3d at 242–43.

C. The Balance of the Equities and Public Interest Favor an Injunction.

A preliminary injunction is in the public interest because, in short, the effects of the requested injunction on the Government pale in comparison to the direct and substantial harms—outlined above—that Plaintiffs will suffer absent the injunction.

Specifically, the public interest favors issuing a preliminary injunction for two reasons. First, the effect of the Drug Companies' policies—*i.e.*, the elimination of certain 340B discounts —is to deprive 340B providers, including the Hospital Plaintiffs and other members of the Association Plaintiffs, of funds otherwise used for care for patients in those providers' vulnerable communities. 340B providers use revenue from the 340B Program to fund uncompensated care that would not otherwise be financially sustainable, often serving the neediest in their communities. *See* Strumwasser Decl., ¶ 12 (If the current restrictions are permitted to continue, or expand to other companies, SMMC's ability to serve the most vulnerable patients will be curtailed or in some cases, eliminated); Holland Decl., ¶ 16 (Avera St. Mary's Hospital will be forced to evaluate and likely curtail some of the important programs through which it provides uncompensated care to the communities it serves); Williams Decl., ¶ 13 (If the current restrictions are permitted to continue, Riverside will be forced to provide fewer services and serve fewer patients).

It is not only in the interest of hospitals, but also in the interest of these communities, and particularly their vulnerable patients, for these critical services to continue. *See State v. Azar*, 385 F. Supp. 3d 960, 978 (N.D. Cal. 2019), *vacated on other grounds sub nom. Cal. ex rel. Becerra v. Azar*, 950 F.3d 1067 (9th Cir. 2020) (finding likely irreparable harm "to California's public health and to [plaintiff]'s organizational mission to promote access to high-quality healthcare); *Children's Hosp. of the King's Daughters, Inc. v. Price*, 258 F. Supp. 3d 672, 692 (E.D. Va. 2017), *aff'd in relevant part, vacated in part* 895 F.3d 615 (4th Cir. 2018) (concluding that public interest factor favored plaintiff

hospital where, "[w]ithout an injunction, the Plaintiff's ability to offer lifesaving medical care may be diminished or delayed, the effects of which will fall upon a particularly vulnerable subset of the general public," and "[t]he harm to the members of the public whose quality of care is diminished . . . cannot be undone").

Second, it is in the public interest for government agencies to lawfully implement the statutes they administer. *See Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013) (noting government "cannot suffer harm from an injunction that merely ends an unlawful practice"); *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) ("There is generally no public interest in the perpetuation of unlawful agency action.") (citations omitted)). As demonstrated above, the policies adopted by the Drug Companies are contrary to law, and the public interest lies in remedying HRSA's unlawful agency action of refusing to bring the Drug Companies into compliance with the 340B statute. *See Scholl v. Mnuchin*, __ F. Supp. 3d __, No. 20-cv-5309, 2020 WL 5702129, at *21 (N.D. Cal. Sept. 24, 2020) ("Significantly, when plaintiffs establish that the government's policy violates federal law, the balance of hardships and public interest tip in their favor."); *see also Ariz. Dream Act Coalition*, 757 F.3d at 1069 ("It is clear that it would not be equitable or in the public's interest to allow the state to violate the requirements of federal law, especially when there are no adequate remedies available.") (internal quotation marks, citation, and alterations omitted).

II. THE COURT SHOULD ADVANCE ITS DETERMINATION OF THE MERITS UNDER RULE 65(a)(2) AND ISSUE A PERMANENT INJUNCTION.

Under Federal Rule of Civil Procedure 65(a)(2), "[b]efore or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing." Advancing a decision on the merits under Rule 65(a)(2) is appropriate when "[t]here are no material factual disputes," "[t]he questions raised by the parties are matters of law, and they

have been fully briefed." *March for Life v. Burwell*, 128 F. Supp. 3d 116, 124 (D.D.C. 2015); *cf. Blockbuster Videos, Inc. v. City of Tempe*, 141 F.3d 1295, 1297 (9th Cir. 1998) (noting on appeal from order granting preliminary injunction that appellate court could "decide the merits of the entire case" because the record "is fully developed, the plaintiff requests both preliminary and permanent relief, and the district court's decision rests primarily on an interpretation of law"). In cases where "an expedited decision on the merits [is] appropriate, Rule 65(a)(2) of the Federal Rules of Civil Procedure provides a means of securing one." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).

This is manifestly a case in which "an expedited decision on the merits [is] appropriate." *Id.* Plaintiffs have raised a purely legal challenge to HRSA's decision with respect to the Drug Companies' policies. The parties are briefing the merits of their dispute. *See March for Life*, 128 F. Supp. 3d at 124 (advancing merits decision under Rule 65(a)(2) where "[t]he questions raised by the parties are matters of law, and they have been fully briefed").

If the Court decides to advance its determination of the merits and to consolidate that determination with Plaintiffs' motion for a preliminary injunction, the Court "do[es] not need to analyze the typical preliminary injunction factors." *March for Life*, 128 F. Supp. 3d at 124; *see also Cardona v. Oakland Unified School Dist., Cal.*, 785 F. Supp. 837, 840 n.6 (N.D. Cal. 1992) (noting distinction between "standard for a preliminary injunction [which] does not require a showing that Plaintiffs will in fact succeed in their ultimate claim for relief, but only a likelihood of success," and standard where there is "consolidation of the preliminary injunction hearing with trial on the merits"); *ApolloMedia Corp. v. Reno*, 19 F. Supp. 2d 1081, 1088 (N.D. Cal. 1998) ("Irreparable injury is required for preliminary injunctions, but once actual success on the merits has been established, a party is entitled to relief as a matter of law irrespective of the amount of irreparable injury which may be shown.") (internal quotation marks omitted) (quoting *Continental Airlines, Inc. v. Intra Brokers, Inc.*,

24 F.3d 1099, 1104 (9th Cir. 1994)). Plaintiffs hereby incorporate their arguments regarding their likelihood of success on the merits, *see supra* Section I.A, as arguments on the merits for purposes of Rule 65(a)(2).

CONCLUSION

For the foregoing reasons, this Court should declare that HRSA's decision that it lacks the authority to require the Drug Companies to provide 340B covered entities with covered drugs at or below 340B ceiling prices when they dispense those drugs through contract pharmacies violates 5 U.S.C. § 706(2)(A). This Court should also order Defendants to require the Drug Companies to provide covered outpatient drugs at or below 340B ceiling prices to covered entities when they dispense those drugs through contract pharmacies. This Court should further order Defendants to require the Drug Companies to refund the Hospital Plaintiffs and the Association Plaintiffs' members the difference between what each covered entity paid for covered outpatient drugs and the 340B ceiling price for Drug Companies' drugs dispensed during the time Drug Companies' illegal policies were in effect. Finally, this Court should order Defendants to refer the matter to the HHS Office of the Inspector General for assessment of civil money penalties pursuant to 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003.

If the Court finds that the decision that HRSA lacks authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices to covered entities that dispense those drugs through contract pharmacies is not a final agency action, then this Court should declare that Defendants' failure to decide whether the Drug Companies' conduct complies with the 340B statute is agency action unlawfully withheld or unreasonably delayed, in violation of 5 U.S.C. § 706(1). It should then order Defendants to issue a decision, within 30 days, on whether the Drug Companies' policies not to sell 340B drugs at or below the 340B ceiling price when dispensed through contract pharmacies comply with the 340B statute and to inform the Court of its decision. Finally, if Defendants determine that the

Drug Companies' conduct violates the 340B statute, the Court should issue an order directing Defendants to inform the Court as to the actions they will take to address that illegal conduct.

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Respectfully submitted,

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